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| 09/996,024      | 11/16/2001  | Allan Svendsen       | 6072.210-US         | 3239             |

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NEW YORK, NY 10110

EXAMINER

KIM, YOUNG J.

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

12

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/996,024

Applicant(s)

SVENDSEN, ALLAN

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 15, 20-22 and 58-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15, 20-22 and 58-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/514,599.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1637

### **DETAILED ACTION**

The instant Office Action responds the Amendment received on July 7, 2003 (Paper No. 11).

#### ***Preliminary Remark***

The Office acknowledges the cancellation of claims 11-14, 16-19, and 23-57; and the addition of claims 58-70.

Rejections hereto not reiterated or maintained are considered to be withdrawn.

#### ***Election/Restrictions***

Applicants are advised that the election requirement made in the Office Action mailed on April 9, 2003 is hereby withdrawn, necessitated by the Amendment received on July 7, 2003, amending claim 10 to become drawn to the subject matter of Group I.

Claims 1-10, 15, 20-22, and 58-70 are pending and are under prosecution therefore.

#### ***Specification***

The objection to the specification for failing to comply with the Sequence Rules as set forth in 37 CFR 1.82(a)(1) and (a)(2), made in the Office Action mailed on April 9, 2003 is withdrawn in view of the Amendment received on July 7, 2003, amending the specification into compliance.

#### ***Claim Rejections - 35 USC § 112 - Maintained***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1637

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1 and its dependent claims 2, 3, 20, and 21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on April 9, 2003 is maintained for the reasons of record.

Applicants' arguments received on July 7, 2003 have been fully considered but they are not found persuasive.

Applicants argue that the claim is not amended to become drawn to the three dimensional structure of SEQ ID NO: 1 depicted in Appendix 1, rendering the claims definite.

This argument is not found persuasive in view of the claim amendment, wherein the preamble recites the phrase, "parent pullulanase has more than 50% homology with the amino acid sequence shown in SEQ ID NO: 1, SEQ ID NO: 3, or SEQ ID NO: 5." Applicants are reminded that the recited SEQ ID Numbers are **DNA** (nucleic acid) sequences, not amino acid sequences.

Although 37 CFR 1.822(c)(3) and MPEP 2423.02 allows the Applicants to recite the amino acids corresponding to the codons in the coding parts of a nucleotide sequence, if Applicants desire to discuss those amino acids in the coding parts of the nucleotide as a separate sequence, those amino acids *must* also be set forth as a *separate sequence* because the amino acid sequence may not be captured in the sequence database if it is only presented in the Sequence Listing as a *mixed* nucleotide and amino acid sequence (MPEP 2423.02).

***Rejection – Necessitated by Amendment***

Claims 4-10, 15, 22, and 58-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants are reminded that the recited SEQ ID Numbers in the above claims are **DNA** (nucleic acid) sequences, not amino acid sequences, rendering the claims indefinite.

Although 37 CFR 1.822(c)(3) and MPEP 2423.02 allows the Applicants to recite the amino acids corresponding to the codons in the coding parts of a nucleotide sequence, if Applicants desire to discuss those amino acids in the coding parts of the nucleotide as a separate sequence, those amino acids ***must*** also be set forth as a ***separate sequence*** because the amino acid sequence may not be captured in the sequence database if it is only presented in the Sequence Listing as a ***mixed*** nucleotide and amino acid sequence (MPEP 2423.02).

***Rejection – Maintained***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-3, 20, and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, made in the Office Action mailed on April 9, 2003 is maintained for the reasons of record.

Art Unit: 1637

Applicants' arguments received on July 7, 2003 have been fully considered but they are not found persuasive.

Applicants are reminded that claimed SEQ ID Numbers are DNA (nucleic acid) sequences. The claimed invention appears to be drawn to modifying the three dimensional structure of a **protein** which is comprised of *amino acid sequences* to produce a protein of altered activity, and reflecting this modified amino acid sequence into a nucleic acid sequence. The Nucleic acid sequence is expressed in a host cell to produce the modified protein with modified activities. However, the claims are drawn to modifying the three-dimensional structure of **DNA sequences**. DNA sequences do not have three-dimensional structures.

As already set forth in the previous Office Action, neither the prior art nor the specification provide for a method of modeling a parent pullulanase based on a three-dimensional structure of a *nucleic acid sequence*. Therefore, it would require undue experimentation of a skilled artisan in the field of protein modeling to practice a method which requires the generation of a three-dimensional structure of a nucleic acid sequence.

With regard to Exhibits, all of the exhibits have been considered but they fail to substantiate Applicants' position that it is possible to construct a three-dimensional structure of a nucleic acid sequence. Exhibit A included only a table of contents which lacked substantive information. Exhibits B and C were articles which discussed protein modeling which involved the comparison of protein sequence, not nucleic acid sequence (see Figure 1).

***Rejection – Necessitated by Amendment***

Art Unit: 1637

Claims 4-10, 15, 22, and 58-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The basis of the rejection has been already addressed above.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Inquiries***


**Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-**

Art Unit: 1637

**3905. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.**

Young J. Kim

10/1/03

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

10/2/03